

Memorandum of Understanding (MoU)
Between
The Brazilian Health Regulatory Agency (ANVISA)
And
The Central Drugs Standard Control Organization (CDSCO),
Directorate General of Health Services (DGHS),
Ministry of Health and Family Welfare,
Government of India

The Brazilian Health Regulatory Agency (hereinafter referred to as “ANVISA”) and the Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India (hereinafter referred to as “CDSCO”), hereinafter jointly referred to as the “Parties”,

TAKING INTO ACCOUNT the Memorandum of Understanding between CDSCO and ANVISA, in the field of pharmaceutical products, signed on October 17th 2016;

CONSIDERING the role of international cooperation on the work of medical products regulatory authorities;

INTENDING to establish a framework for the exchange of information in the field of medical products, including pharmaceutical ingredients, drugs and biological products and medical devices;

DESIRING to strengthen their communication to facilitate and promote access to safe, effective and quality medical products within their countries;

Have reached the following understanding:

Clause I: Scope

1. This Memorandum of Understanding (MoU) provides a framework for voluntary information exchange and regulatory cooperation, to the extent jointly decided by the Parties, in accordance with their respective laws, regulations, and mandates.
2. This MoU covers regulatory activities of the Parties relating to medical products, acknowledging that each Party may have jurisdiction over specific categories of products and may apply different definitions under their respective legal frameworks, including but not limited to matters related to:

- Regulatory policies;

- Guidelines and standards;
- Good Laboratory and quality control practices;
- Good Pre-market assessment and approval practices;
- Post-market surveillance, including pharmacovigilance and materiovigilance;
- ATR for the enforcement activities undertaken for the products of concern for each party;
- Good Manufacturing Practices (GMP);
- Good Clinical Practices;
- Good Regulatory Practices;
- Pharmacopoeial standards, including reference to national or internationally recognized pharmacopoeias.

3. This MoU does not constitute a treaty or an international agreement, nor does it create obligations under international law between the Parties.

4. This MoU is not intended to create any legally binding obligations to share confidential information between the Parties, nor does it impose any mutual financial obligations. It does not restrict the Parties' powers granted by the laws and regulations in their respective countries to fulfill their respective responsibilities.

5. This MoU will be carried out in accordance with the respective laws and regulations of the two countries, and subject to the availability of appropriate funds and personnel of the Parties.

6. The following items are excluded from the scope of this MoU and will not be exchanged in any case:

- Personal information or related to the privacy of an individual, such as medical files;
- Confidential information shared by a third party within the framework of any confidentiality agreement.

7. This MoU does not grant any rights to the receiving Party towards the information shared under its scope, whether such information is confidential or not.

Clause II: Information exchange

1. Each Party understands that information exchanged between them may include confidential information that is not available in public domain in the country of the Party providing the information. The Parties note that it is essential that confidential information emanated from one Party will be treated as such by the other Party and shall not share with the third party without the written consent of the parties providing such information.

2. Each Party shall prevent: (a) the public release of confidential information that has been shared for the purposes set out in this Memorandum; and (b) any other release of this information for purposes not set out in this Memorandum.

Clause III: Duration of confidentiality commitment

1. The confidentiality commitment in relation to confidential information transmitted within the framework of this MoU is not limited in time.
2. Notwithstanding the termination of this MoU, the Parties will continue to protect confidential information against unauthorized disclosure or unauthorized use.

Clause IV: Contact Points

The liaison officers responsible for the administration of this MoU are:

- a) For the Indian Party, the Deputy Drugs Controller (India), International Cell, CDSCO(HQ), New Delhi (internationalcell@cdsco.nic.in);
- b) For the Brazilian Party, the Head of International Affairs Office (rel@anvisa.gov.br).

Clause V: Financial arrangements

Each Party will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MoU.

Clause VI: Entry and Exit of Personnel

1. Each Party, in accordance with its national laws and regulations, shall make its best efforts to support the other Party, within the scope of its responsibilities, in providing the necessary facilities for the entry, stay, and exit from its territory of personnel from the other Party who officially participate in the cooperation activities under this MoU.
2. The Parties agree that the entry, stay, and exit of personnel who officially participate in the activities related to this MoU shall be handled with the competent authorities of the host Party, in accordance with the applicable rules and procedures.
3. The entry, stay, and exit of such personnel shall be subject to immigration, tax, customs, health, and national security regulations in force in the territory of the host Party, and the personnel shall not engage in any activities unrelated to their official duties.





Clause VII: Cooperation initiatives

Any cooperation initiatives arising from the signing of this MoU shall be previously agreed upon by the Parties and formalized through a specific work plan, jointly developed. The implementation of such initiatives shall be subject to mutual interest, as well as the availability of human, materials and financial resources from both Parties.

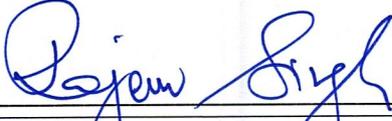
Clause VIII: Dispute Resolution

1. The present Memorandum is not considered as an international treaty and does not create rights and obligations under international law.
2. Any dispute between the Parties arising out of the implementation, application or interpretation of this MoU shall be settled amicably through direct consultation or negotiation between the Parties through diplomatic / official channels.

Clause IX: Entry into effect, duration, renewal and amendment

1. This MoU will become effective on the date of signature by the Parties.
2. This MoU will remain in effect for five (5) years after signature and will be automatically renewed for successive periods of five (5) years each at a time, unless either Participant formally notifies the other Participant, in writing, of its intention not to renew this MoU, at least three (3) months in advance.
3. Any amendment to this MoU will be made under mutual written consent of the Parties.
4. This MoU may be terminated at any time by either Party upon thirty (30) days written notice.

Signed on 18th of February 2026, with two original copies in the Portuguese, Hindi, and English languages, all texts being equally authentic. In the event of divergence in the interpretation of this MoU, the English text shall prevail.

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| Leandro Pinheiro Safatle Director-President | Dr. Rajeev Singh Raghuvanshi Drugs Controller General |
| For the Brazilian Health Regulatory Agency (ANVISA) | For the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services (DGHS) |